

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
10 March 2005 (10.03.2005)

PCT

(10) International Publication Number  
**WO 2005/020823 A1**

(51) International Patent Classification<sup>7</sup>: **A61B 17/00**,  
17/06

(21) International Application Number:  
PCT/NL2004/000584

(22) International Filing Date: 19 August 2004 (19.08.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
1024218 3 September 2003 (03.09.2003) NL

(71) Applicant (for all designated States except US): **STICHT-  
ING SINT ANNADAL** [NL/NL]; Blankenberg 1,  
NL-6267 NN Cadier en Keer (NL).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **BAETEN, Cornelius,  
Gerardus, Maria, Ignatius** [NL/NL]; St. Hubertuslaan  
11, NL-6211 KC Maastricht (NL).

(74) Agents: **DOHMEN, Johannes, Maria, Gerardus et  
al.**; Algemeen Octrooi- en Merkenbureau, P.O. Box 645,  
NL-5600 AP Eindhoven (NL).

(81) Designated States (unless otherwise indicated, for every  
kind of national protection available): AE, AG, AL, AM,  
AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,  
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,  
GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,  
KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD,  
MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG,  
PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM,  
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM,  
ZW.

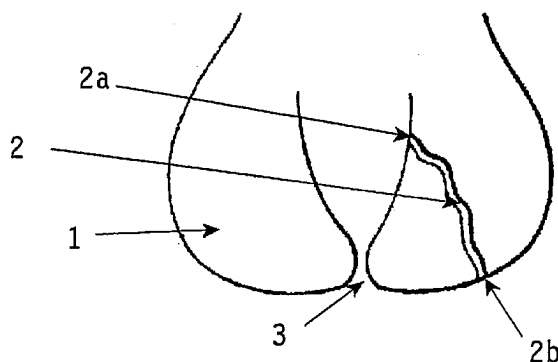
(84) Designated States (unless otherwise indicated, for every  
kind of regional protection available): ARIPO (BW, GH,  
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,  
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),  
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,  
FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI,  
SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,  
GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guid-  
ance Notes on Codes and Abbreviations" appearing at the begin-  
ning of each regular issue of the PCT Gazette.

(54) Title: **DEVICE FOR TREATING FISTULAS**



(57) Abstract: The invention relates to a device for treating fistulas, in particular a patient's perianal fistulas, which device comprises an elongated probe having a first end and a second end, which probe can be inserted into the entrance of the fistula channel with its first end via the external opening of the fistula in the patient's skin, in the direction of the internal opening of the fistulas inside the patient's body, for the purpose of passing a drainage thread through the fistula channel. The object of the invention is to provide a device for the treatment of fistulas, in particular perianal fistulas, which enables a painless treatment that can be carried out without anaesthesia, and to that end the drainage thread is attached to the second end of the elongated probe. This embodiment obviates the need for surgical treatment. The drainage thread is thus passed through the fistula channel, via the external fistula opening, by the elongated probe. By removing the probe from the patient's body via the internal, anal fistula opening and the anus, the two thread ends (one thread end projecting from anus and the other thread end extending from the external fistula opening) can be connected or tied together. This embodiment does not require surgery under anaesthesia, and in addition it is much less painful for the patient.

WO 2005/020823 A1

Device for treating fistulas.

### DESCRIPTION

The invention relates to a device for treating fistulas, in particular a patient's perianal fistulas, which device comprises an elongated probe having a first end and a second end, which probe can be inserted into the entrance of the fistula channel with its first end via the external opening of the fistula in the patient's skin, in the direction of the internal opening of the fistulas inside the patient's body, for the purpose of passing a drainage thread through the fistula channel.

Such a device is known, for example from Spanish patent No. ES-2116914 A1. In said patent it is proposed to insert an elongated probe into the fistula channel with its first, free end, using an auxiliary device. After removal of the probe via the anus, a cutting tool provided with a drainage thread is attached to the auxiliary device that projects from the interior, anal opening of the fistula. By subsequently withdrawing the auxiliary device through the fistula channel in the direction of the external fistula opening, the tissue directly surrounding the fistula channel is surgically removed by the cutting tool on the one hand, whilst on the other hand a drainage thread is pulled through the passage that has thus been surgically created.

The drainage thread thus provided remains behind in the surgically treated fistula channel for some time to contribute to the healing process.

The device proposed in ES-2116914 A1 requires surgery, which surgery generally causes the patient so much pain that it must be performed under anaesthesia.

Another painful surgical treatment is stretching the fistula channel by means of clamps for the purpose of passing a drainage thread therethrough, one end of which thread is connected or tied to the

thread end that projects from the external fistula opening via the internal, anal fistula opening and the anus. This treatment, too, is preferably carried out under anaesthesia. In addition, the use of clamps may cause damage to the wall of the fistula channel, which interferes with the healing process.

The object of the invention is to obviate the above drawbacks and to provide a device for the treatment of fistulas, in particular perianal fistulas, which enables a painless treatment that can be carried out without anaesthesia.

According to the invention, the drainage thread is attached to the second end of the elongated probe. When this embodiment is used, surgery is no longer required. The drainage thread is thus passed through the fistula channel by the elongated probe via the external fistula opening. By withdrawing the probe from the patient's body via the internal, anal fistula opening and the anus, the two thread ends (one thread end extending from the anus and the other end extending from the external fistula opening) can be connected or tied together.

This embodiment does not require surgery under anaesthesia and is much less painful for the patient.

In a more specific, very functional embodiment, the drainage thread is permanently attached to the second end of the elongated probe. More in particular, the drainage thread is permanently glued, welded or clamped to the second end of the elongated probe. These embodiments guarantee a secure connection with the probe and prevent the drainage thread from unexpectedly becoming detached from the probe. In addition, the external diameter of the second end of the probe can thus remain within bounds, which prevents the wall of the fistula channel from being damaged upon passage of the probe through the fistula channel.

In the clamped embodiment, the second end of the elongated probe is partially hollow for receiving the drainage thread. A correct, secure attachment of the drainage thread to the second, hollow end of the

probe is thus guaranteed in that the hollow second end of the elongated probe is according to the invention partially closed, for example by means of a punching technique.

5 A smooth treatment can be obtained if according to the invention the elongated probe is at least partially flexible. The elongated probe may be made of a plastic material in that case.

In a specific embodiment, however, the plastic probe may exhibit a certain degree of rigidity, or be made of a metal, for example, in order to enable manipulation of the probe through the fistula channel.

10 The insertion of the elongated probe into the fistula channel can be slightly facilitated in that the elongated probe narrows in the direction of the first end in one embodiment.

More specifically, the first end is knob-shaped.

15 The invention will now be explained in more detail with reference to a drawing, in which:

Figs. 1a-1d schematically show the steps of the treatment of a fistula, using a device according to the invention;

Fig. 2 schematically shows a first embodiment of a device according to the invention for treating fistulas.

20 Fig. 1a shows the lower part of the body 1 of a patient suffering from a perianal fistula 2. The perianal fistula 2 has an internal fistula opening 2a, which is in contact with the intestinal canal 3, and an external fistula opening 2b in the patient's skin.

25 For the treatment of said perianal fistula, using the present invention, a method is proposed which on the one hand is considerably less painful for the patient and which on the other hand can be carried out without anaesthesia.

30 The treatment comprises the insertion of an elongated probe 4 having a first distal end 4a and a second end 4b via the external fistula opening 2b.

In the course of the treatment, the doctor attending the

patient will remove the elongated probe 4 from the body 1 via the internal fistula opening 2a and the anus 3, as is shown in Fig. 1c.

To that end, the probe 4 may be made of a flexible material, for example a plastic, so as to make it possible to manoeuvre the elongated probe 4 in the patient's rectum.

In order to make it possible on the other hand to pass the probe 4 through the fistula channel 2, the elongated probe 4 must exhibit a certain degree of rigidity in longitudinal direction. In a specific embodiment, the elongated probe 4 may to that end be made of a plastic material, or be configured as a metal rod, for example.

Once the elongated probe 4 has been removed from the patient's body 1 via the anus 3, as is shown in Fig. 1c, the two ends 5a and 5b, respectively, of the drainage thread 5 may be interconnected, for example by tying them together in a knot 5c, as is shown in Fig. 1d. The presence of a drainage thread 5 in the fistula channel 2 ensures that the fistula channel 2 will remain open for some time, thus preventing inflammations and the like. The latter has a very beneficial effect on the healing process.

According to the invention, the drainage thread 5 is fixedly connected to the end 4b of the elongated probe 4 with its first end 5a. A glueing or welding technique may be used for this purpose (the latter technique is very suitable if the elongated probe 4 is made of a plastic material). On the other hand, the drainage thread may also be permanently clamped to the end 4b of the probe 4. Said end 4b may be hollow for that purpose, for receiving the end 5a of the drainage thread 5. By subsequently closing the hollow end 4b by means of a suitable tool, for example a punch, the end 5a of the drainage thread 5 is clamped down in the probe 4, which prevents the drainage thread 5 from becoming detached upon insertion of the probe 4 and the drainage thread 5 into the fistula channel 4.

The thread 5 may be a Seton thread, for example.

Fig. 2 shows an embodiment of an elongated probe 4 having a hollow end 4b, into which the end 5a of the drainage thread 5 has been inserted. The end 4b has subsequently been closed by means of a clamping or punching technique, thus clamping down the wire end 5a in the probe 4.

5 As is clearly shown in Figs. 1a-1d and Fig. 2, the diameter of the probe 4 decreases from the end 4b in the direction of the free end 4a.

On the other hand, the free end 4a of the elongated probe 4 is knob-shaped, as a result of which the wall of the fistula channel 2 is slightly stretched (without causing damage to the tissue, however) upon  
10 insertion of the probe 4 into the fistula channel 2, so as to facilitate insertion of the probe 4.

It will be apparent that the need for otherwise painful surgical treatments is obviated by using this probe. In addition, the  
15 treatment of a fistula no longer needs to take place under anaesthesia when using the device according to the invention. The latter alleviates the patient's discomfort to a significant extent, whilst in addition the treatment of a fistula no longer needs to take place in a hospital, but can also be carried out at the patient's home by the family doctor.

## CLAIMS

1. A device for treating fistulas, in particular a patient's perianal fistulas, which device comprises an elongated probe having a first end and a second end, which probe can be inserted into the entrance of the fistula channel with its first end via the external opening of the fistula in the patient's skin, in the direction of the internal opening of the fistulas inside the patient's body, for the purpose of passing a drainage thread through the fistula channel, **characterized in that** the drainage thread is attached to the second end of the elongated probe.
2. A device according to claim 1, **characterized in that** the drainage thread is permanently attached to the second end of the elongated probe.
3. A device according to claim 2, **characterized in that** the drainage thread is permanently glued to the second end of the elongated probe.
4. A device according to claim 2, **characterized in that** the drainage thread is permanently welded to the second end of the elongated probe.
5. A device according to claim 2, **characterized in that** the drainage thread is permanently clamped to the second end of the elongated probe.
6. A device according to claim 5, **characterized in that** the second end of the elongated probe is partially hollow so as to receive the drainage thread.
7. A device according to claim 6, **characterized in that** the hollow second end of the elongated probe is partially closed, for example by means of a punching technique.
8. A device according to any one or more of the preceding claims, **characterized in that** the elongated probe is at least partially flexible.

9. A device according to claim 8, **characterized in that** the elongated probe is made of a plastic material.

10. A device according to claim 9, **characterized in that** the plastic probe has a rigid core, for example made of a metal.

5 11. A device according to any one or more of the preceding claims, **characterized in that** the elongated probe narrows in the direction of the first end.

12. A device according to any one or more of the preceding claims, **characterized in that** the first end is knob-shaped.



1 / 3

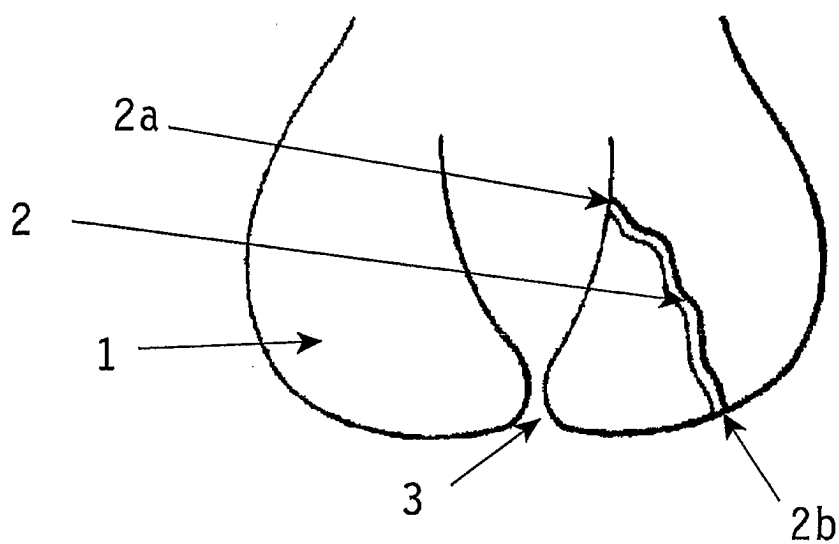


Fig. 1a

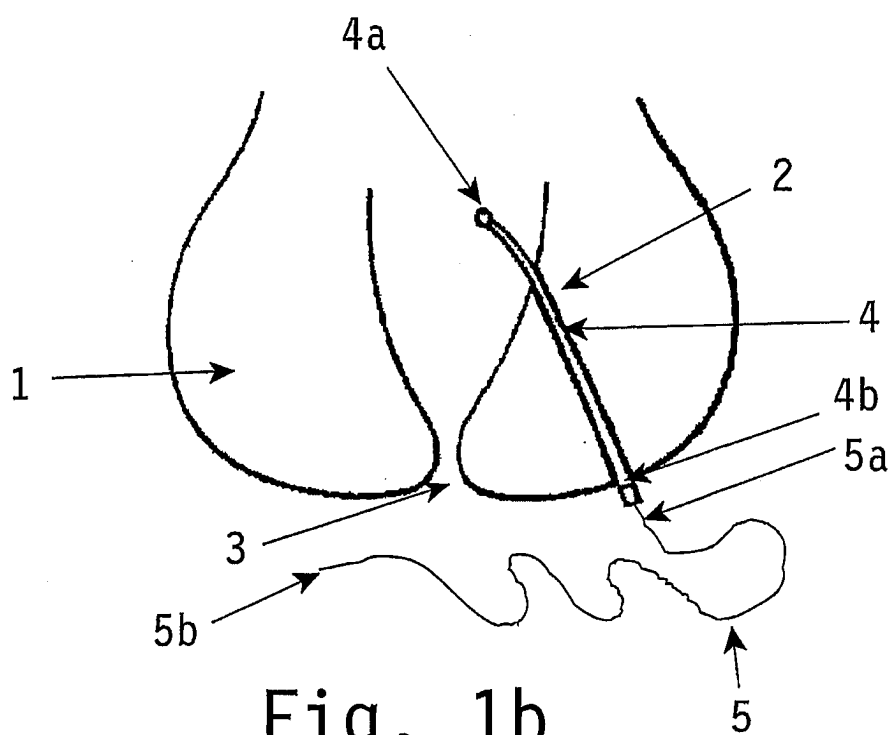


Fig. 1b

2 / 3

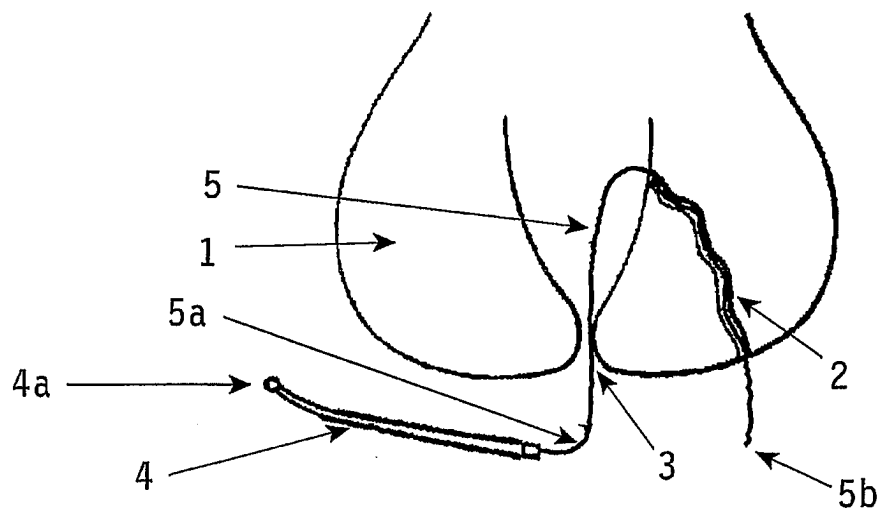


Fig. 1c

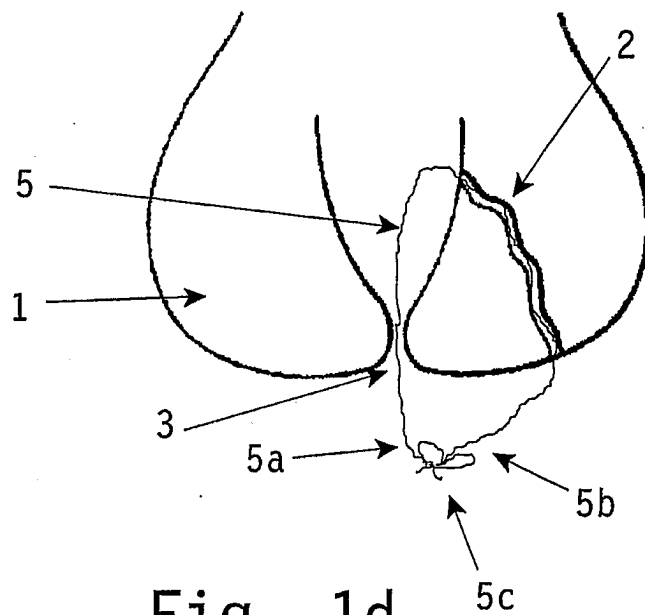


Fig. 1d

3 / 3

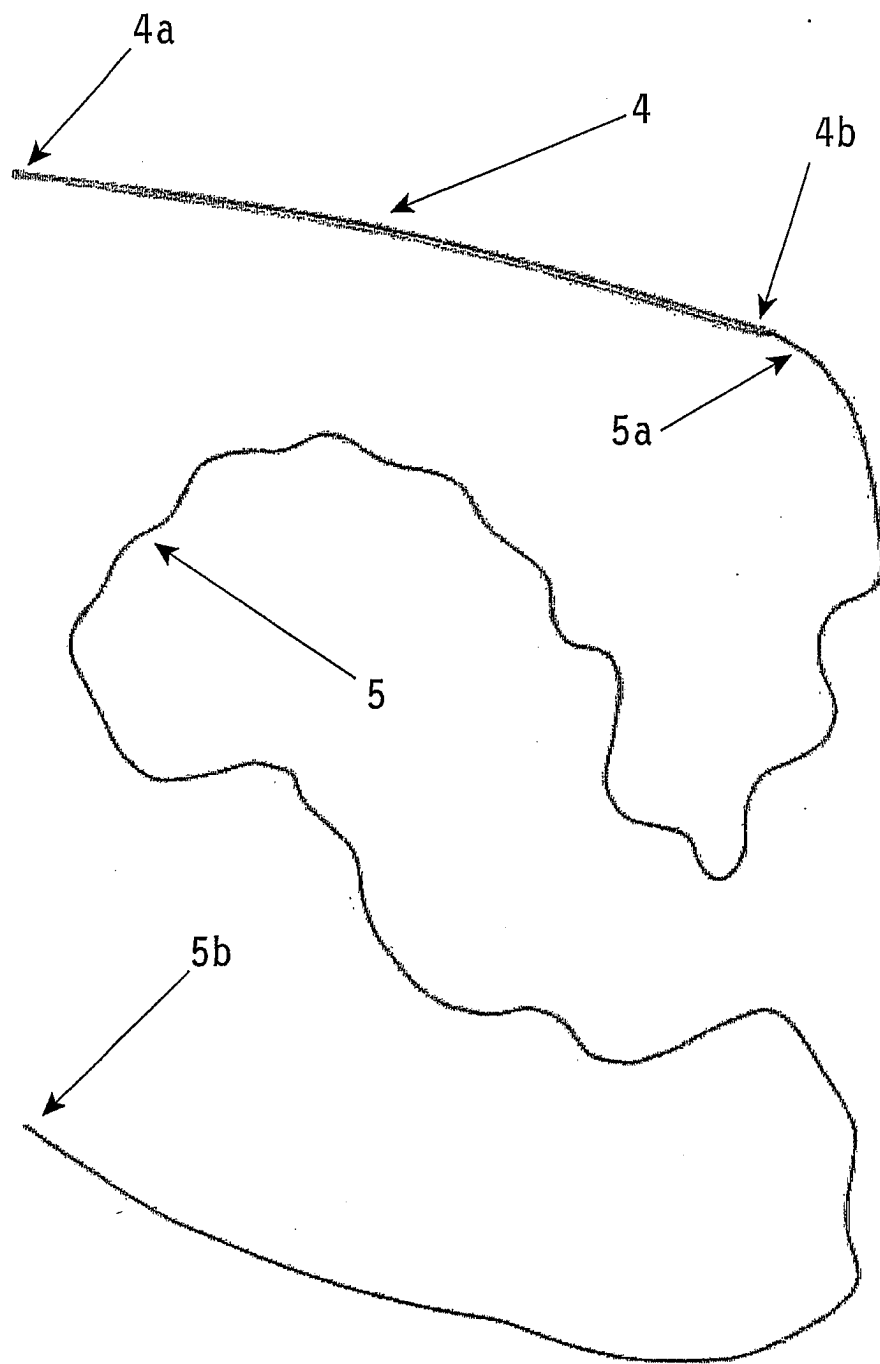


Fig. 2

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/NL2004/000584

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC 7    A61B17/00    A61B17/06		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) IPC 7    A61B		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the International search (name of data base and, where practical, search terms used)  EPO-Internal, PAJ, WPI Data		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 454 327 A (BROWN) 16 June 1891 (1891-06-16) the whole document	1,8-12
A	ES 2 116 914 A (PALAZON HERNANDEZ) 16 July 1998 (1998-07-16) cited in the application the whole document	1
A	GB 2 097 260 A (DOW CORNING CORPORATION) 3 November 1982 (1982-11-03) abstract; figures page 1, lines 105-115	1
A	US 3 420 237 A (FORTAY ET AL.) 7 January 1969 (1969-01-07) the whole document	1
-/-		
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C.		
<input checked="" type="checkbox"/> Patent family members are listed in annex.		
* Special categories of cited documents :		
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>*A* document defining the general state of the art which is not considered to be of particular relevance</p> <p>*E* earlier document but published on or after the International filing date</p> <p>*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>*O* document referring to an oral disclosure, use, exhibition or other means</p> <p>*P* document published prior to the International filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>*T* later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>*G* document member of the same patent family</p> </div> </div>		
Date of the actual completion of the international search  <div style="text-align: center;">22 November 2004</div>		Date of mailing of the international search report  <div style="text-align: center;">03/12/2004</div>
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer  <div style="text-align: center;">Giménez Burgos, R</div>

## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/NL2004/000584

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 1 316 291 A (TSUKADA MEDICAL RESEARCH CO., LTD.) 4 June 2003 (2003-06-04) abstract; figures paragraph '0022! -----	1
A	DATABASE WPI Section PQ, Week 200355 Derwent Publications Ltd., London, GB; Class P32, AN 2003-582660 XP002276609 "Rubber string for anal-fistula ligation" & JP 2003 210502 A (YUFU SEIKI KK) 29 July 2003 (2003-07-29) abstract; figures -----	1

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/NL2004/000584

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 454327	A		NONE	
ES 2116914	A	16-07-1998	ES 2116914 A1	16-07-1998
GB 2097260	A	03-11-1982	BE 892965 A1	26-10-1982
			FR 2504384 A1	29-10-1982
			JP 57183848 A	12-11-1982
US 3420237	A	07-01-1969	NONE	
EP 1316291	A	04-06-2003	WO 03000143 A1	03-01-2003
			CA 2422574 A1	14-03-2003
			EP 1316291 A1	04-06-2003
JP 2003210502	A	29-07-2003	NONE	